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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/552,156 | 10/11/2005 | Andreas Meinke | 05-747 | 4561 |

20306 7590 02/21/2008

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| EXAMINER | |
|---|---|
| BASKAR, PADMAVATHI | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/552,156 | MEINKE ET AL. | |
| | Examiner | Art Unit | |
| | Padmavathi v. Baskar | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *38,40,41,43-46 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40,41,43-46 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants submission filed on 11/27/07 has been entered.

### *Status of claims*

2. The amendment filed on 11/27/07 has been entered.
Claims 1-37, 39 ,42 and 47 are cancelled.
Claims 38, 40, 41,43 and 44 have been amended
Claims 38, 40, 41, 43, 44-46 and 48 are pending and are under examination.

### *Specification Informalities*

3. It is noted that the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. For example:

a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see in particular at least page 39. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP § 608.01.

### *Sequence Requirements*

b In order to have compact prosecution a first office action can be performed on this application, however, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Although the claims in the instant application are not drawn to specific sequences, the disclosure contains sequence that needs sequence identification number on page 39. Applicant is reminded to check the entire disclosure to ensure that the application is in sequence compliance.

APPLICANT IS GIVEN THE TIME ALLOTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Applicant's cooperation is requested in correcting these errors.

***Claim Rejections - 35 USC 112, first paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38, 40, 41, 43-46 and 48 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The newly amended claims are drawn to

a) a polypeptide identified by SEQ ID NO. 243;

b) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 1-285 of the amino acid sequence identified by SEQ ID NO: 243; or

c) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243 , said isolated *S. pneumoniae* polypeptide that is Sp 2216 polypeptide identified by SEQ ID NO: 243, said antigen is a peptide fragment defined by amino acids 1-285 of SEQ.ID.NO:243, However, the claim language "identified by" "defined by" " a polypeptide identified by" "an amino acid sequence defined by" embraces fragments, variants, analogs and homologs etc and also " an amino acid" reads on fragments of the recited fragments and thus broadens the scope of the claims.

Applicant's show support for the amendments presented therein can be found, *inter aria,* in the specification on p. 30, paragraph 1 and in Tables 1 and 2. A review of the specification on p. 30, paragraph 1 and in Tables 1 and 2 does not show support for the claimed language

as discussed above. Further , the limitation " antigenic peptide fragment 101-151" claimed in claims 38 and 43-46 and 48 has no clear support in the specification and the claims as originally filed. Applicants pointed to support for the claimed peptide fragment 101-151 *inter aria,* in the specification on p. 30, paragraph 1 and in Tables 1 and 2. A review of the specification Table 2 discloses support for a peptide fragment 101-121 but not for peptide fragment 101-151. The subject matter claimed in claims 38, 40, 41, 43-46 and 48 broadens the scope of the invention as originally disclosed in the specification.

6. Claims 38 , 40, 41, 43-46 and 48 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for a purified and isolated hyperimmune serum-reactive *S. pneumoniae* antigen that is immunologically reactive with sera from a human having an *S. pneumoniae* infection or an uninfected healthy human, the antigen comprising

a) the amino acid sequence ,SEQ ID NO:243;

b) an antigenic peptide fragment consisting amino acids 1-285 of the amino acid sequence SEQ ID NO: 243; or

c) an antigenic peptide fragment consisting of amino acids 15-37, 32-57, 101-121, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243, wherein each of said polypeptides or antigenic peptide fragment is capable of eliciting an immunological reaction in a human, and a pharmaceutical composition comprising isolated *S. pneumoniae* antigen comprising the amino acid sequence ,SEQ ID NO:243 and a pharmaceutically acceptable carrier said pharmaceutical composition further comprising an immunostimulatory substance said compositions a vaccine does not reasonably provide enablement for a purified and isolated hyperimmune serum-reactive *S. pneumoniae* antigen that is immunologically reactive with sera from a human having an *S. pneumoniae* infection or an uninfected healthy, the antigen comprising an isolated S. *pneumoniae* polypeptide or peptide fragment thereof that is:

a) a polypeptide Sp 2216 identified by SEQ ID NO. 243;

b) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 1-285 of the amino acid sequence identified by SEQ ID NO: 243; or

c) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243, wherein each of said polypeptides or antigenic peptide fragments comprises an epitope capable of eliciting an immunological reaction in a human, said antigen is an isolated polypeptide that is Sp2216 identified by SEQ ID NO. 243, said antigen is antigenic peptide

fragment defined by amino acids 1-285 of SEQ ID NO. 243, said antigen that is an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243t , and a pharmaceutical composition comprising said isolated *S. pneumoniae* antigen (claims 38, a, b , c, 40, 41, 43), said pharmaceutical composition further comprising an immunostimulatory substance, said composition is a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims are drawn to a purified and isolated hyperimmune serum-reactive *S. pneumoniae* antigen that is immunologically reactive with sera from a human having an *S. pneumoniae* infection or an uninfected healthy human, the antigen comprising an isolated *S. pneumoniae* polypeptide or peptide fragment thereof that is: the antigen comprising an isolated S. *pneumoniae* polypeptide or peptide fragment thereof that is:

a) a polypeptide Sp 2216 having an amino acid sequence identified by SEQ ID NO. 243;.
b) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 1-285 of the amino acid sequence identified by SEQ ID NO: 243; or
c) an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID

NO. 243, wherein each of said polypeptides or antigenic peptide frequents comprises an epitope capable of eliciting an immunological reaction in a human and a pharmaceutical composition comprising said antigenic fragment said pharmaceutical composition further comprising an immunostimulatory substance a peptide containing at least two Lys-Leu-Lys motifs, said composition is a vaccine.

The specification teaches *S.pneumoniae* antigen having the 392 amino acid sequence SEQ.ID.NO:243 . The specification also discloses antigenic peptide fragment consisting of amino acids 1-285 of the amino acid sequence , SEQ ID NO: 243 or an antigenic peptide fragment consisting of amino acids 15-37, 32-57, 101-121, 115-135, 138-158, 152-172, 220-242 or 236-258 of the amino acid sequence , SEQ ID NO: 243 ( see Table 2) and are reactive to hyperimmune sera in an ELISA assay that could be used in a diagnostic assay. However the specification fails to disclose *S.pneumoniae* antigenic peptide fragment comprising an amino acid sequence defined by amino acids 1-285 of the amino acid sequence identified by SEQ ID NO: 243; or an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243 that are *reactive* to hyper immune serum as these fragments include not the recited peptide fragments but also other amino acid sequences that are unknown . The specification contemplates identification of conserved antigens inducing antibodies that are cross-reactive with different clinical isolates is crucial for the development effective vaccines and is especially relevant for protein-based vaccines targeting pneumococcal diseases, since more then 90 different serotypes of *S. pneumoniae (Pneumococcus)* have been associated with human infections.

One cannot extrapolate the teaching of the specification to the scope of the claims because the claims as written recite the claim language " polypeptide identified by" and "an amino acid sequence defined by" embraces fragments, variants, analogs and homologs etc and also " an amino acid" reads on fragments of the recited fragments. As drawn to peptide fragments ,variants etc, Colman et al. (see reference in 12/5/06 office action, Research in Immunology, 1994; 145(1): 33-36) teach that a single amino acid change in an antigen can effectively abolish antibody antigen binding. Furthermore, Abaza et al. (see reference in 12/5/06 office action, Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444, see abstract in particular) teach single amino acid change outside the antigenic site on a protein affects antibody binding. Clearly if antibody binding is abolished, it is because of the alteration

of the conformation of the epitope to which the antibody binds. Given the clear teaching drawn to conformation alteration with even a single amino acid change, clearly it would be expected that fragments, variants, analogs and homologs etc of SEQ.ID.NO:243 would alter the conformation of that epitope in the peptide fragment and that it could not be predicted, nor would it be expected that a structurally altered antigenic epitope that would bind to hyperimmune serum obtained from *S.pneumoniae* infected or exposed human that can be used alone or in a pharmaceutical composition as claimed and no evidence has been provided which would allow one of skill in the art to predict which of the broadly claimed peptide fragments would function as claimed with a reasonable expectation of success. In view of the unpredictability of the art , the lack of teachings of the specification, it would require undue-experimentation on the part of the skilled artisan to practice the invention as claimed. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

***Response to Applicants arguments:***

Applicant states 11/27/07 that the specification provides clear guidance to one of skill in the art for making the explicitly-recited antigenic peptide fragments of the polypeptide of SEQ ID NO: 243 and demonstrates immune response thereto. For example, the specification in Example 3 (and corresponding results shown in Table 1 on p. 73) shows regions of the polypeptide that are identified as immunogenic. In Example 4 (and corresponding results shown in Table 2 on p. 80) the specification discloses specific serum reactive epitopes. In addition, Example 7 (on p. 58) shows that the highest degree of protection was achieved by antigens representing SEQ ID NO: 243 (SP2216) along with other antigens. More specifically, Fig. 10 shows protection by the full length polypeptide of SEQ ID NO: 243 and fragments thereof. The specification further teaches one of ordinary skill in the art how to use the explicitly-recited antigenic peptide fragments of the polypeptide of SEQ ID NO: 243 to generate an immune response in an animal, as well as substitutions that can be made within SEQ ID NO: 243 to maintain its antigenicity (e.g., p. 20, paragraph 6 and p. 23, last paragraph). Furthermore, the specification at Example 4, Table 2 (p. 80) shows that antigenic fragments of SEQ ID NO: 243 could be detected by using human antisera, indicating that humans are capable of generating and in fact do generate an immune response to the polypeptide and antigenic fragments of SEQ ID NO: 243.

Applicants argument are considered but found to be nonpersuasive because, the claim language "identified by" "defined by" " a polypeptide identified by" "an amino acid sequence defined by" embraces fragments, variants, analogs and homologs etc and also " an amino acid" reads on fragments of the recited fragments. The scope of the claims are much broader than the specification as the specification teaches only a purified and isolated hyperimmune serum-reactive *S. pneumoniae* antigen comprising the amino acid sequence ,SEQ ID NO. 243, an antigenic peptide fragment consisting of amino acids 1-285 of the amino acid sequence SEQ ID NO: 243; or an antigenic peptide fragment consisting of amino acids 15-37, 32-57, 101-121, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243 (Table 2 ) as pointed by the applicant. However, the specification does not teach fragments, variants, analogs and homologs. Further, the specification fails to teach the pharmaceutical composition, vaccine comprising said variants etc . In view of the unpredictability of the art , the lack of teachings of the specification, it would require undue-experimentation on the part of the skilled artisan to practice the invention as claimed

***Claim Rejections - 35 USC 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38 , 40, 41, 43, 44-45 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Masignani et al WO 02/077021, 3 rd Oct 2002 ((see reference in 12/5/06 office action).

Claims 38, 40, 41, 43, 44-45 and 48 are drawn to a purified and isolated hyperimmune serum-reactive *S. pneumoniae* antigen that is immunologically reactive with sera from a human having an *S. pneumoniae* infection or an uninfected healthy human, the antigen comprising an isolated *S. pneumoniae* peptide fragment thereof that is an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243, wherein each of said polypeptides or antigenic peptide frequents comprises an epitope capable of eliciting an immunological reaction in a human, said polypeptide is identified by SEQ.ID.NO:243, said fragment is defined

by amino acids 1-285 of SEQ.ID.NO:243, wherein *S. pneumoniae* antigen according to claim 38 that is an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243 and a pharmaceutical composition comprising said purified and isolated *S. pneumoniae* antigen peptide fragments and optionally a pharmaceutically-acceptable carrier or excipient said pharmaceutical composition further comprising an immunostimulatory substance, said composition is a vaccine.

(Please note , the claim language "identified by" "defined by" " a polypeptide identified by" "an amino acid sequence defined by" embraces fragments, variants, analogs and homologs etc and also " an amino acid" reads on fragments of the recited fragments).

Masignani et al WO 02/077021 (PD 03-OCT-2002) disclose as shown below an isolated *S.pneumoniae* antigen , SEQ.ID.NO: 4652 which is 100% identical to the claimed polypeptide (Sp 2216), SEQ .ID.NO:243 as well as peptide fragments of SEQ.ID.NO:243 which are interpreted to read upon the claimed isolated *S. pneumoniae* polypeptide that is Sp 2216 polypeptide identified by SEQ ID NO: 243 or antigenic fragment defined by amino acids 1-285 of SEQ.ID.NO;243 or an antigenic peptide fragment comprising an amino acid sequence defined by amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243 (The transitional limitation "comprises" similar to the limitations, such as, "has"," includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]).

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  Streptococcus pneumoniae; type 4 strain.
PD   03-OCT-2002, WO200277021-A2.
Masignani V,  Tettelin H,  Fraser C;
SEQ ID NO 4652; 56pp; English.
\
  Query Match             100.0%;  Score 1927;  DB 6;  Length 392;
  Best Local Similarity   100.0%;  Pred. No. 1.1e-127;
  Matches  392;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MKKKILASLLLSTVMVSQVAVLTTAHAETTDDKIAAQDNKISNLTAQQQEAQKQVDQIQE 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MKKKILASLLLSTVMVSQVAVLTTAHAETTDDKIAAQDNKISNLTAQQQEAQKQVDQIQE 60

Qy         61 QVSAIQAEQSNLQAENDRLQAESKKLEGEITELSKNIVSRNQSLEKQARSAQTNGAVTSY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 QVSAIQAEQSNLQAENDRLQAESKKLEGEITELSKNIVSRNQSLEKQARSAQTNGAVTSY 120

Qy        121 INTIVNSKSITEAISRVAAMSEIVSANNKMLEQQKADKKAISEKQVANNDAINTVIANQQ 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 INTIVNSKSITEAISRVAAMSEIVSANNKMLEQQKADKKAISEKQVANNDAINTVIANQQ 180

Qy        181 KLADDAQALTTKQAELKAAELSLAAEKATAEGEKASLLEQKAAAEAEARAAAVAEAAYKE 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db        181 KLADDAQALTTKQAELKAAELSLAAEKATAEGEKASLLEQKAAAEAEARAAAVAEAAYKE 240

Qy        241 KRASQQQSVLASANTNLTAQVQAVSESAAAPVRAKVRPTYSTNASSYPIGECTWGVKTLA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 KRASQQQSVLASANTNLTAQVQAVSESAAAPVRAKVRPTYSTNASSYPIGECTWGVKTLA 300

Qy        301 PWAGDYWGNGAQWATSAAAAGFRTGSTPQVGAIACWNDGGYGHVAVVTAVESTTRIQVSE 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 PWAGDYWGNGAQWATSAAAAGFRTGSTPQVGAIACWNDGGYGHVAVVTAVESTTRIQVSE 360

Qy        361 SNYAGNRTIGNHRGWFNPTTTSEGFVTYIYAD 392
              ||||||||||||||||||||||||||||||||
Db        361 SNYAGNRTIGNHRGWFNPTTTSEGFVTYIYAD 392
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Thus the prior art read on the claims 38, 40, 41 and 43 . The teaching of the Masignani et al disclose that the pharmaceutical compositions comprise therapeutic amount of peptide SEQ.ID.NO: 4652 (see page 20 under pharmaceutical compositions) in a pharmaceutically acceptable carrier and thus read on claim 44. This composition is a vaccine composition as it used for therapeutic or preventive disease (see page 20, lines 21-32) it meets the limitations of claim 48. Further, the art reads on claim 45 as the composition comprise immunostimulatory agents (see page 21, lines 10-50) such as bacterial cell walls, muramyl peptides and adjuvants etc. Thus, the prior art anticipated the claimed invention.

Applicants state 11/27/07 that Masignani reference discloses the amino acid sequence of an open reading frame of *S. pneumoniae* genomic DNA without disclosing whether in fact this polypeptide is actually produced by the bacteria. Moreover, the reference fails to disclose that the putative polypeptide is antigenic. Further, the Masignani reference fails to provide any teaching with regard to antigenic peptide fragments, particularly fragments that could produce protective immunogenic response. In particular, the Masignani reference does not identify any antigenic fragments and specifically reactive with hyperimmune sera. Thus, the Masignani reference does not disclose each and every limitation of Applicants' claims as required under 35 U.S.C. §102(b).

Applicant's argument is considered but found to be nonpersuasive because the art teaches the polypeptide and antigenic fragments as recited in the claims. Claims are not limited to specific fragments and the polypeptide is identical to the polypeptide claimed polypeptide, whether it is produced by Bactria or not. The art discloses an isolated *S.pneumoniae* antigen , SEQ.ID.NO: 4652 and is 100% identical to the claimed product polypeptide Sp 2216 SEQ .ID.NO:243 and peptide fragment defined by amino acids 1-285 of . SEQ .ID.NO:243 .As the art discloses the same polypeptide obtained from *Streptococcus pneumoniae* and is identical to the claimed peptide fragments comprising 15-37, 32-57, 101-151, 115-135, 138-158, 152-172,

220-242 or 236-258 of SEQ ID NO. 243 , it is expected to bind to the hyperimmune serum as it is known in the immunology art that even a peptide with 5-10 amino acids induce an immune response. Therefore, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

***Remarks***

9. No claims are allowed.

***Conclusion***

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

Respectfully,

/Padma v Baskar/

Examiner, Art Unit 1645
Padma Baskar Ph.D.